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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/065,330	04/23/1998	AMEAE M. WALKER	2500.097US2	7326

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EXAMINER

SAUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/065,330

Applicant(s)
WALKER

Examiner
Christine Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 26, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 January 2002 and 26 March 2002 has been entered.
2. Claims 1-6 and 9-11 are pending in the instant application.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed 24 January 2002 have been fully considered but they are not deemed to be persuasive.

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Claim Rejections - 35 USC § 103

6. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cooke et al. (U.S. Pat. No. 4,725,549) and A. M. Walker (TEM, 5(5): 195-200) in view of Maciejewski et al. (J. Biol. Chem. 270(17): 27661-27665, 1995, for the reasons of record in paper #13, 16 and 25.

Applicant argues at page 2 of the response that there is no motivation to combine Maciejewski and Walker and that Maciejewski teaches away from the combination. Applicant asserts that Maciejewski "teaches that serine 90 is the critical phosphorylated residue in prolactin and that substitution of other phosphorylated residues does not mimic the biological effect of phosphorylated prolactin". These arguments are not persuasive for the following reasons. First, Maciejewski et al. does not teach that serine 90 is the critical phosphorylated residue in prolactin, but rather, that it happens to be the major site of phosphorylation in **bovine** prolactin. Walker also recognizes that serine 90 in bovine prolactin is the "most favored site", but that the serine at position 177 (with reference to the rat sequence, corresponding to position 179 in the human) is "critical for biological activity of the molecule" and is a major site of phosphorylation (see page 196, column 3 of Walker). Maciejewski et al. was not cited for a teaching of substitution of position 179 in human prolactin, only for the teaching that substitution of serine mimics phosphorylation. Walker was cited for the teaching that a serine in prolactin within the region of amino acids 170-180 is highly conserved between species and is a major site of phosphorylation.

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Applicant argues at page 2 that one of skill in the art would not believe that serine 179 and serine 90 are equivalent. This argument is not persuasive because the major phosphorylation site in bovine prolactin is at the serine residue at position 90, and substitution of this position mimics phosphorylation. One can reasonably conclude that substitution of the major phosphorylation site in prolactin from another species in the manner taught by Maciejewski et al. would also lead to mimicry of the phosphorylation. The criticality of the amino acid position is taught by Walker, and the modification of the phosphorylated amino acid is taught by Maciejewski.

Applicant argues at page 3 of the response that Maciejewski only teaches that substitution of serine 90 mimics phosphorylation. Applicant further asserts that Maciejewski does not teach that substituted prolactin mimics phosphorylation. This assertion is contradicted by the title of the Maciejewski reference which states "Mutation of Serine 90 to Glutamic Acid Mimics Phosphorylation of Bovine Prolactin". As to the assertion that only substitution of serine 90 mimics phosphorylation, Applicant is again directed to Walker which identifies the major site of phosphorylation in bovine as serine 90 and the equivalent major phosphorylation site in rat as corresponding to position 177, which is position 179 in the human.

Applicant again argues that Maciejewski does not teach substitution of any other amino acid other than the serine at position 90. Applicant is again reminded that Maciejewski et al. was not cited for its teaching of substitution of a particular amino acid, but rather that substitution of the major phosphorylation site, being serine 90 in bovine prolactin, mimicked the effects of phosphorylation. Applicant's insistence that "Maciejewski teaches that serine at position 90 is the

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only critical residue and the only residue whose substitution can mimic phosphorylation" is short-sited, and is not consistent with the teachings in the prior art. Maciejewski, as well as Walker, identify the serine at position 90 in bovine prolactin as the major phosphorylation site. Maciejewski is silent to the major phosphorylation sites in other species of prolactin. However, Walker makes it clear that serine 177 (as numbered in rat prolactin) is a major site of phosphorylation, which is distinct from bovine prolactin. It is not clear why bovine prolactin is phosphorylated differently from other prolactin molecules, but it does not teach away from modifying other prolactin molecules in a similar manner, i.e. by substitution of the major phosphorylated serine residue, in order to mimic the phosphorylation. Suggestion is in the art and there is a reasonable expectation of success as set forth in the grounds of rejection and there is ample motivation as also set forth, absent evidence to the contrary.

Conclusion

7. No claim is allowed.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud